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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/620,607	07/20/2000	Glenn Friedrich	LEX-0032-USA	3266

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Lexicon Genetics Incorporated
4000 Research Forest Drive
The Woodlands, TX 77381

EXAMINER

NGUYEN, DAVE TRONG

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/620,607

Applicant(s)

FRIEDRICH ET AL.

Examiner

Dave T. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12/2/00. 6) ☐ Other: _____

Claims 2-6 have been canceled, claims 1 and 7 have been amended by the amendment filed October 15, 2003.

Applicant's election without traverse of the claimed invention as claimed in the presently remaining claims 1 and 7 in the response filed October 15, 2003 is acknowledged.

Claims 1 and 7 are pending for examination.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is written so as not to claim SEQ ID NO: 34 *per se* but to sequences that "correspond" to SEQ ID NO: 34. The "corresponding" is not an art-recognized term, and the specification does not provide any closed definition for the term. The "corresponding" is vague and its meaning is indefinite, and thus, it is not apparent as to what are exactly the metes and bounds of sequences that applicant intended for the breadth of claim 1.

35 USC 101:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 7 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial utility. The instant application mainly provides a high-throughput protocol using a gene trapped retroviral vector to generate a library of mutagenized mouse ES cell clones, wherein sequence analysis was employed to sequences trapped genes, identified as SEQ ID NOS: 1-1848. The as-filed application then contemplates that the described mutated ES cells would provide a valuable resource for defining, evaluating, or validating the biological function or disease/pharmaceutical relevance of each of these genes. However, not only that no particularly biological function of SEQ ID NO: 34 was present in the as-filed specification, there is no description of any biological function, or disease/pharmaceutical relevance of any of the claimed mutagenized cell or ES cell.

It is clear from the instant specification that the gene described as SEQ ID NO: 34 are claimed could a biological function that is relevant to purposes of drug discovery. There is little doubt that, after complete characterization, this SEQ ID NO: 34 and its ES mutagenized clones, the claimed cells may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete, and thus, lacks a substantial and specific utility for the claimed invention at the time the invention was

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made. The instant situation is directly analogous to that which was addressed in Brenner v. Manson, 148 U.S.P.Q. 689 (Sup. Ct, 1966). The court expressed the opinion that all chemical compounds are "useful" to the chemical arts where this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. 101 which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. Note that a utility that requires or constitutes carrying out further research or identify or reasonably confirm a real world context of use is not a substantial utility.

The as-filed specification does not provide any information or written support to show a substantial utility for the subject matter being sought in the presently pending claims. The specification as a whole clearly generalizes and merely speculates a number of potential general utilities, wherein no specific or substantial usages of the claimed cells are described. In order to utilize any of the claimed cell in a specific and substantial usage, a skilled artisan would have to require an additional knowledge about the specifically biological function of not only SEQ ID NO: 34, but also of the claimed cells. However, there is no evidence that such are found in the as-filed specification, and thus, the utility requirement has not been met, e.g., where applicant's asserted utilities constitute research on the claimed product itself, there is not apparent *immediate* benefit to the public that the patent system is designed to protect.

In view of the reasons set forth in the stated rejection and in view of the reasons set forth in the preceding paragraphs, a skilled artisan would not have recognized that, at the time the invention was made, this as-filed specification provides any substantial

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evidence for a substantial and specific utility for the subject matter being sought in the presently pending claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1, readable on genes and/or sequences which are not necessarily SEQ ID NO: 34, and/or a genus of mutagenized cells, are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The as-filed specification does not meet the written description requirement for claiming a genus of nucleotide sequences that correspond to SEQ ID NO: 34, nor does it meet the requirement for claiming a genus of mutagenized mammalian cells. An adequate written description of the invention defined by the claims requires more than a mere statement that it is part of the invention and reference to potential methods and/or assays and/or formula containing unspecified molecular structures of nucleotide sequences and/or cells that are essential for the making the genuses of unspecified

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material(s) as claimed; what is required is the knowledge in the prior art and/or a description as to the availability of a representative number of species of biochemical or molecular structures, e.g., primary sequence structures and/or structures identifiable as the mutagenized element. In this instance, the as-filed specification only discloses a mutagenized mouse ES cell clone containing SEQ ID NO: 34.

It is not sufficient to support the present claimed invention directed to numerous number of nucleotide sequence(s) or cell cloned as claimed, with no specific chemical structure so as to exhibit one of applicant's intended utilities, because disclosure of no more than that, as in the instant case, is simply a wish to know the identity of any and/or all other material(s) of nucleotide sequence(s) and/or clones of muagenized cells. In light of the fact that the claimed genus is enormous, wherein each of the species embraced by the genus involves a number of specific biological functions but distinct biological functions, one skilled in the art would not have recognized that the as-filed specification has provided sufficient description of a representative number of clones that contain a mutagenized sequence "corresponding" to SEQ ID NO: 34. Claiming unspecified molecular structures of gene(s) that must possess any of the biological properties as contemplated by applicant's disclosure without defining what means will do so is not in compliance with the written description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with

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sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998). The skilled artisan cannot envision the detailed structure of a representative number of clones that contain a mutagenized sequence "corresponding" to SEQ ID NO: 34. Therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the structures and/or methods disclosed in the as-filed specification. Thus, In view of the reasons set forth above, one skilled in the art at the time the invention was made would not have recognized that applicant was in possession of the claimed invention as presently claimed.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051**.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is **(703) 305-7401**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Please note that the examiner is expected to move to a new US PTO office building located in Alexandria on January 12, 2004. The examiner office phone number at the new building is **571-272-0731**.



DAVE T. NGUYEN
PRIMARY EXAMINER

Dave Nguyen
Primary Examiner
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